REMARKS

I. Status of the Application

Claims 1 – 17 are presently pending in the application. Claims 1, 2, 9, and 10 have been amended. Claims 1 – 9, 11, 13 – 15, and 17 stand rejected under 35 U.S.C. §102(b) as being anticipated by Dunn et al., WO/91/01126. Claims 10, 12, and 16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Dunn et al., WO/91/01126.

Applicants have amended the claims to more clearly define and distinctly characterize Applicants' novel invention. Support for the amendments can be found throughout the specification and claims as originally filed. Specifically, support for the amendment to claims 1, 2, 9, and 10 to recite "a rigid matrix component" can be found in the specification at least at page 2, lines 14 – 18 ("A sufficient rigidity of the membrane is thus a requirement") and page 5, lines 5 – 7 ("the implant can at its shaping stage very easily be shaped into the required shape and yet its rigidity is sufficient to support or attach tissue during healing"; page 15, lines 3 – 6 ("the membrane of the invention can be made so thick that its rigidity is sufficient to support tissue during regeneration..."); and Table 1, page 11. As is readily seen from these examples, the specification provides support for "a rigid matrix component" because the plasticizer is adapted to reduce substantially the rigidity of the implant, and therefore it naturally follows that the matrix component is rigid when the plasticizer is dispersed therein.

Support for the amendment to claims 1, 2, 9, and 10 to recite, "a plasticizer dispersed within the rigid matrix" or "which plasticizer is dispersed within the rigid matrix" can be found at least at Example 1 page 9, lines 34 – 35 ("to ensure diffusion of NMP to the polymer"); page 11, lines 10 – 12 ("the NMP content of the material is approximately 45 percent by weight from the total mass of NMP and the matrix material"); Example 2 page 11 lines 28-30 where the

plasticizer is mixed with the melt form of the polymer in an extruder; and page 14, lines 2 – 5 ("[t]he samples were immersed in an NMP solution for 40 seconds, after which the samples were lifted on top of a metal net for 30 minutes to ensure the diffusion of NMP to the polymer."). As readily seen from these examples, the specification contains support for the plasticizer being dispersed within the rigid matrix whether by diffusion as is the soaking method or by mixing with an extruder.

The amendments presented herein add no new matter.

Applicant respectfully requests entry and consideration of the foregoing amendments, which are intended to place this case in condition for allowance.

II. Claims 1 – 9, 11, 13 – 15, and 17 Are Novel Over Dunn et al

At page 2, paragraph 2 of the instant Office Action, claims 1 – 9, 11, 13 – 15, and 17 stand rejected under 35 U.S.C. §102(b) as being anticipated by Dunn et al., WO/91/01126. The Examiner is of the opinion that Dunn et al. discloses a biodegradable system for regenerating the periodontium comprising a polymeric matrix along with various other solvents and components. The Examiner states that the polymers of Dunn et al are selected from polylactides, polyglycolides, and polyamides and that N-methyl-2-pyrrolidone is recited as a solvent in the system and that once "implanted/injected into the body the solvents dissipate leaving a more rigid polymer comprising a porous polymer with bioactive agents such as growth hormones and/or antimicrobial agents lodged within the polymeric matrix." The Examiner asserts that claims 1 – 8 are product claims and it is "irrelevant the order in which the product is made." The Examiner further asserts that claims 6 and 7 are product by process claims, and that patentability is determined based on the product itself, not based on its method of production. Applicants

respectfully traverses the Examiner's rejections. Applicants respectfully submit that for a reference to anticipate a claim, the reference must teach each and every element of the claim.

Claim 1 is directed to a biodegradable implant comprising ***a rigid matrix component***, whereas Dunn et al is directed to a composition that is in ***liquid form*** and is not a biodegradable implant comprising ***a rigid matrix component***.

Dunn et al teach that "precise cutting of membranes and placement over the treatment site can be difficult, time consuming and unpredictable in therapeutic outcomes (page 2, lines 5 – 7). Dunn et al further state that the ***liquid system*** was developed to "overcome placement difficulties inherent in non-liquid systems." (page 2, lines 32 – 33). Thus, the liquid system of the Dunn reference is not an implant comprising ***a rigid matrix component***. Accordingly, Dunn et al is not concerned with inserting into an organ system implants comprising ***rigid matrix components***. Instead, the ***liquid system*** of Dunn et al is injected into a site in liquid form to overcome the difficulties of non-liquid systems, i.e., rigid implants. (page 2, lines 22 – 33). Thus Dunn et al do not teach rigid biodegradable implants comprising ***a rigid matrix component***.

In addition, Dunn et al do not teach a plasticizer dispersed within the rigid matrix, nor the effects on rigidity of the matrix imparted by the plasticizer before or after implantation. Instead Dunn et al, as discussed above, teach a liquid system. Applicants note that at page 4, lines 12 – 14, Dunn et al disclose that the liquid system can be set outside the body, but nowhere does Dunn teach the claimed rigid matrix with the plasticizer dispersed therein. The only method Dunn et al teach for setting the liquid is dissipation of solvent out of the polymer. See discussion at page 4 lines 6-11.

As Dunn et al fails to teach each and every element of Applicants' claims, Applicants request that the rejection of claims 1 – 9, 11, 13 – 15, and 17 under 35 U.S.C. §102(b) be reconsidered and withdrawn.

III. Claims 10, 12, and 16 Are Patentable Over Dunn et al

At page 3, paragraph 3 of the instant Office Action, claims 10, 12, and 16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Dunn et al., WO/91/01126. The Examiner states that claims 10 and 12 are drawn to methods of manufacture where the plasticizer is added to the implant after the implant is formed. The Examiner further states that claim 16 is drawn to a method where the plasticizer is mixed with the active agent, then mixed with the polymer. The Examiner asserted that Dunn et al disclosed a biodegradable implant used for rebuilding tissue, where the implant comprises N-methyl-2-pyrrolidone, which dissipates from the implant upon placement in the body. The Examiner admits that Dunn et al do not disclose the order of manufacture. The Examiner instead asserts that it would have been obvious to one of ordinary skill in the art to manipulate the order of the procedure, in order to determine the most effective manufacturing method, and to follow the teachings and suggestions of Dunn in order to rebuild periodontal tissue after surgery. The Examiner further asserted that a skilled artisan would have expected to attain a porous, biodegradable implant useful in rebuilding periodontal tissue after dental surgery.

Applicants respectfully traverse the Examiner's rejections. To render a claim obvious, all the claim limitations must be taught or suggested by the prior art. As discussed above, Dunn et al. fails to teach or suggest a biodegradable implant comprising ***a rigid matrix component*** or ***a plasticizer dispersed within the rigid matrix***, as required by the instant claims.

The Examiner asserts that it would have been obvious to manipulate the order of the procedure to determine the most effective manufacturing method. Applicants respectfully disagree. Instead of teaching an implant, as asserted by the Examiner, Dunn et al teach quite the contrary. Dunn et al teach a liquid system that overcomes the difficulties of precise cutting and placement of implants over treatment sites (page 2, lines 5 – 7), and that the invention, a biodegradable ***liquid polymer system***, is substantially different from the polylactic acid **membranes** described in the literature. (Page 3, lines 30 – 32). Based on the teachings of Dunn et al, one of skill in the art would conclude that forming an implant or membrane from a rigid matrix component prior to insertion into the surgical site was undesirable. It is therefore, an unexpected result in support of non-obviousness that Applicants' implants are useful for implantation into surgical sites for rebuilding tissue. In addition, Dunn et al's disclosure of setting the liquid outside the body, as discussed above, does not teach Applicant's plasticizer being dispersed within the rigid matrix because Dunn et al's set liquid would not contain any plasticizer. One having skill in the art would not be motivated to disperse plasticizer within the polymer of Dunn et al because of the teaching that to set the liquid, the solvent must dissipate from the polymer.

Accordingly, Dunn et al. fails to render the claimed invention obvious. Therefore, Applicants respectfully request the Examiner to withdraw the rejection of claims 10, 12, and 16 under 35 U.S.C. §103(a).

IV. CONCLUSION

Having addressed all outstanding issues, Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

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John P. Iwanicki, Reg. No. 34,628
BANNER & WITCOFF, LTD.
28 State Street, 28th Floor
Boston, MA 02109
Telephone: (617) 720-9600